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Wyoming Pharmacists Administer Adult Immunizations

By Crystal Huntrods, PharmD Candidate

On January 17, 2007, Governor Dave Freudenthal signed into law the right for pharmacists to administer immunizations under the Wyoming Pharmacy Act, Statute 33-24-157, and Chapter 16 of the Rules and Regulations of the Act. A licensed Wyoming pharmacist, interested in immunizing, must first become registered with the Wyoming State Board of Pharmacy. As of 2010, some 113 pharmacists – about 10% of the total licensed pharmacists in Wyoming – are registered in Wyoming to immunize. Currently, pharmacy interns cannot administer immunizations in the state of Wyoming.

Ten different immunizations are listed for a pharmacist to prescribe, dispense, and administer to healthy adults, age 19 or older, with no contraindications. The immunizations, as listed in Chapter 16, Section 2(c), include:

1. Tetanus, diphtheria, pertussis (Td, Tdap),
2. Measles, mumps, rubella (MMR),
3. Varicella,
4. Influenza,
5. Pneumococcal (polysaccharide),
6. Hepatitis A,
7. Hepatitis B,
8. Meningococcal,
9. Human papillomavirus (HPV), and
10. Zoster

Wyoming pharmacists cannot immunize children, defined as anyone 18 years old or younger, and may only dispense and administer an immunization to "high risk" adults with a physician's prescription. To qualify to immunize, a pharmacist in Wyoming must meet a set of requirements. Such requirements include completion of an immunization program provided by the American Pharmacists Association, the Washington State Pharmacy Association's program, or the *Drug Store News* immunization program approved by the Board. The pharmacist must also be certified in CPR, which can be completed through the American Heart Association or the American Red Cross. The pharmacist must also complete at least one continuing education contact hour on a topic related to immunizations. A registration application may be acquired from the Wyoming State Board of Pharmacy Web site. Registration must be renewed annually, on or before December 31, and a $10 fee is required. In the past, pharmacies were required to use the *Immunization Questionnaire and Vaccine Consent Form* provided by the Board, but with rule revisions in 2009, pharmacies providing immunizations need only to have the Board approve the individualized form.

A recent Issue Brief, entitled *Adult Immunization: Shots to Save Lives*, published by the Trust for America's Health, the Infectious Diseases Society of America, and the Robert Wood Johnson Foundation provides a glimpse at recent immunization statistics for both Wyoming and the nation. The brief suggests some 40,000 to 50,000 adult deaths in the country each year that can be attributed to "vaccine preventable diseases," and about $10 billion is spent annually treating these diseases. The report also addresses information from the 2007 National Immunization Survey, published by the Centers for Disease Control and Prevention (CDC), finding:

- only 2.1% of eligible adults (18 to 64 years old) had the tetanus, diphtheria, and whooping cough vaccine in the previous two years;
- just under 2% of older patients (60 years old and over) had the shingles (zoster) vaccine; and
- only 10% of eligible adult women (18 to 26 years old) had the HPV vaccine.

As of 2008, 66.9% of adults 65 years and older had received the pneumococcal vaccine in the United States; in Wyoming 70.3% had received the vaccine. The percentage is much lower than the CDC's current goal of 90%. In the same year, only 36.1% of all adults, 18 years and older, had received the influenza vaccine; in Wyoming 39.5% had received the vaccine. With adult immunization rates shown to be low in the past, Wyoming pharmacists now have an important role and opportunity to not only help educate adults about what immunizations they are eligible to receive, but also to prescribe and administer these vaccinations to healthy adults.

What Can Be Changed on a Schedule II Prescription in Wyoming

On November 17, 2007, Drug Enforcement Administration (DEA) published in the *Federal Register* that pharmacists should not change the essential components of a Schedule II prescription after oral communication with the physician including the "name of the controlled substance, strength, dosage form, and quantity prescribed, and the earliest date on which the prescription may be filled." DEA had previously stated that the same changes could be made to Schedule II prescriptions as to Schedule III, IV, and V

continued on page 4

FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.*

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see *www.ismp.org/Tools/confuseddrugnames.pdf* for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when Norvasc® is entered into the computer, a formulary note screen appears, alerting the pharmacist that Norvasc often looks like Navane® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at *www.fda.gov/AboutFDA/WhatWeDo/track/default.htm*. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm*, Center FDA-TRACK Program Areas available at *www.fda.gov/*

AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor® (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin® which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5 % to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at *http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml*.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

continued from page 1

prescriptions creating confusion on the matter. After this issuance DEA has repeatedly advised that pharmacists adhere to current state regulations. The Wyoming State Board urges pharmacists to **continue following state law on this issue.** In Chapter 6, Section 11 (f)(i), it states that "after consultation/approval of the prescribing practitioner the pharmacist is permitted to change the following: **Drug strength; Drug quantity; Directions for use; and Dosage form**" and all changes must be documented on the face of the hard copy and should include "the date, name of the person consulted, and initials of the pharmacist." The pharmacist may also change "the patient's address with proper verification" without consultation with the provider.

E-Prescribing of Controlled Substances

By Cody Plaisted, PharmD Candidate

On June 1, 2010, DEA implemented a new rule allowing for the electronic prescribing of controlled substances, including Schedule II medications. The purpose of this change, according to the *Federal Register* published on March 31, 2010, was to reduce potential prescription forgery, reduce errors caused by illegible handwriting and misunderstood oral prescriptions, and increase efficiency while decreasing the amount of time patients spend waiting for prescriptions.

Under **Wyoming state law this type of prescribing is still prohibited for scheduled medications.** The Wyoming State Board of Pharmacy, in collaboration with a task force, is working on new legislation and rule changes to allow for e-prescribing for scheduled drugs. The hope of this committee is to have the changes ready to present at the legislative session in February 2011. DEA has set forth certain standards that will be required by physicians and pharmacies to be implemented before e-prescribing of controlled substances will be allowed. The complete list of requirements for pharmacies that will process e-prescriptions can be found in 21 CFR 1211.205. The general requirements include an application that can import, display, and store the required contents of a controlled substance prescription as well as sign and archive the prescription. The application must also be able to store all information required by DEA to be annotated on the prescription and limit access for the annotation, alteration, or deletion of prescriptions to certain individuals or roles, such as a pharmacist or pharmacy technician. The application must also have an internal audit trail that documents what has happened to the prescription and the system must perform daily internal audits and generate reports showing any potential security problems that are identified for pharmacy review. The application providers will have to hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. Without this report stating that the application meets the standards set forth by DEA, a pharmacy cannot accept e-prescriptions for controlled medications. To be certain if the system you may have at your pharmacy meets these requirements, you would need to contact your application provider and obtain a copy of the audit report.

For the practitioner to be able to e-prescribe scheduled medications, certain requirements will be necessary. First, the physician will have to go through identity proofing and logical control access. Third parties that are approved federally will do these steps. Identity proofing is the process of identifying the person as the person whom he or she claims to be. Logical control access is the process of verifying that the user has the authority to perform the requested application.

After these steps are completed, a two-factor credential would be created for a provider based on something the provider knows, like a password, and something the provider has, such as a PDA or USB drive that has a cryptographic key stored in the device that the provider would possess. Both items would be needed for a provider to process and sign a prescription for a controlled substance electronically.

With the standards that are being set in place, e-prescribing of scheduled medications should be a safe and more effective way of providing controlled substance prescriptions to patients. For further information about e-prescribing contact the Wyoming State Board of Pharmacy, or to view the final ruling in its entirety visit the Office of Diversion Control Web site at *www.DEAdiversion.usdoj.gov* and select "Electronic Prescriptions for Controlled Substances."

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